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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,195	10/31/2003	Linda M. Pacioretty	CLANACCR_001NP	4532

7590 04/13/2007
John G. Babish
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EXAMINER

CHONG, YONG SOO

ART UNIT	PAPER NUMBER
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1617

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/699,195	PACIORETTY ET AL.	
	Examiner	Art Unit	
	Yong S. Chong	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 1-20, 25-27, 30-31, 36-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-24, 28, 29, 32-35, 39 and 40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's response filed on 2/7/2007. Applicant's election **with** traverse of the restriction requirement in the reply is acknowledged. The traversal is on the ground(s) that (1) the effect of thiol compounds does not lend itself to being used for dietary supplements and (2) there is no undue burden to search for the groups concurrently. This is not found persuasive because one skilled in the art would recognize the incorporation of thiol-containing compounds in dietary supplements. Furthermore, a search for one group will not lead to information regarding another as evidenced by their divergent subject matter and classification. The requirement is still deemed proper and is therefore made FINAL.

Claim(s) 1-40 are pending. Claim(s) 1-20, 27, 30-31, 38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claim(s) 25-26, 36-37 are withdrawn from further consideration as being drawn to a non-elected species. Claim(s) 21 (in part), 22-24, 28-29, 32 (in part), 33-35, 39-40 are examined herein insofar as they read on the elected invention and species.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been

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obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham vs John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim(s) 21 (in part), 22-24, 28-29, 32 (in part), 33-35, 39-40 are rejected under 35 U.S.C. 103(a) as being obvious over McCleary (US Patent Application 2002/0132219 A1) in view of Applicant's admission of the prior art.

The instant claims are directed to a method for treating, preventing, or normalizing fat maldistribution or hyperlipidemia resulting from anti-retroviral treatment of HIV-1 infection in a subject by administering triglyceride of conjugated linoleic acid and a thiol-containing compound.

McCleary teach a nutritional supplement composition comprising conjugated linoleic acid and alpha-lipoic acid for modulating nutrient partitioning in a human (abstract). Disorders of nutrient partitioning include obesity (fat maldistribution) and hyperlipidemia (section 0002). More particularly, it is desirable to provide a means for modulating aberrant pathways of nutrient partitioning so as to avoid excessive fat storage, to promote oxidation of fat, and reduce fat levels (sections 0006 to 0007). McCleary also discloses specifically triglyceride of conjugated linoleic acid (section 0010). McCleary also teach that fat synthesis and storage are diminished resulting in a

fall in the intracellular fat content of the liver, pancreas, and skeletal muscle as well as a fall in visceral fat and total body fat stores accompanied by a decrease in individual fat cell volume (section 0023). Preferred amounts for CLA are 50 mg to 20 g and for alpha-lipoic acid are 25 mg to 2 g (Table 1).

However, McCleary fail to disclose specifically fat maldistribution or hyperlipidemia resulting from anti-retroviral treatment of HIV-1 infection in a subject.

Applicant's disclosure of the prior art teaches that HIV infection is accompanied by disturbances in lipid and glucose metabolism. These metabolic abnormalities are further confounded by hypercholesterolemia, hypertriglyceridemia, and hyperlipidemia induced by anti-retroviral drugs. In fact, it is estimated that almost two-thirds of HIV/AIDS patients exhibit abnormal fat distribution coincident with AR-therapy (section 0003 to 0009).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to administer a nutritional supplement composition comprising conjugated linoleic acid and alpha-lipoic acid to treat a subject with fat maldistribution and hyperlipidemia resulting from anti-retroviral treatment of HIV-1 infection.

A person of ordinary skill in the art would have been motivated to administer a nutritional supplement composition comprising conjugated linoleic acid and alpha-lipoic acid to treat a subject with fat maldistribution and hyperlipidemia resulting from anti-retroviral treatment of HIV-1 infection because: (1) McCleary teaches the treatment of fat maldistribution and hyperlipidemia by administering a nutritional supplement

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composition comprising conjugated linoleic acid and alpha-lipoic acid, and (2)

Applicant's admission of the prior art teaches that fat maldistribution and hyperlipidemia are common in HIV/AIDS patients who are receiving anti-retroviral treatment.

Therefore, one of ordinary skill in the art would have had a reasonable expectation of success in treating not only patients suffering from fat maldistribution and hyperlipidemia, but also from patients suffering from fat maldistribution and hyperlipidemia resulting from anti-retroviral treatment of a HIV-1 infection.

Conclusion

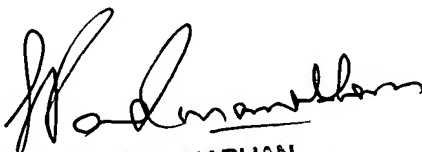
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

YSC



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER